Medtronic News

Medtronic Technologies Improve Delivery of Cardiac Resynchronization Therapy

First-of-its-Kind Data on EffectivCRT(TM) for Heart Failure Patients with Atrial Fibrillation Presented at ESC

DUBLIN and ROME - Aug. 29, 2016 - Medtronic plc (NYSE:MDT) today announced results from the Cardiac Resynchronization Therapy Efficacy Enhancement (CRTee) study. The study showed that the Medtronic-exclusive device-based EffectivCRT(TM) during AF algorithm improves therapy delivery in heart failure patients with atrial fibrillation (AF). The results were presented at the 2016 European Society of Cardiology (ESC) Congress in Rome.

Current CRT devices report "percent pacing" - a measure of whether the device sends a pacing pulse to stimulate the heart.

However, current devices do not report the effectiveness of each pacing stimulus - that is, whether the pacing pulse "captures" the heart muscle and improves its pumping ability.

The new EffectivCRT during AF feature automatically determines the effectiveness of each left ventricular pace and adjusts pacing rates during AF. This is important for heart failure patients suffering from AF, because the pacing pulse from the device is more likely to be ineffective or interrupted because of this irregular heart rhythm.

"This technology brings us one step closer to understanding effective left ventricular pacing for AF patients receiving CRT, which has been difficult to manage in the past" said Suneet Mittal, M.D., director, Electrophysiology Laboratory, Arrhythmia Institute of the Valley Health System, Ridgewood, NJ. "We can now optimize treatment to a larger patient base, including difficult-to-treat non-responders, to hopefully prevent patients from undergoing additional treatments and often invasive follow-on procedures."

The EffectivCRT Diagnostic and EffectivCRT during AF algorithm are available on the Claria MRI(TM) Quad CRT-D SureScan(TM) in Europe. *The EffectivCRT features are investigational only in the United States; the Claria CRT-D is not approved for sale in the U.S.* The Claria device, which is approved for full-body MRI scans in 1.5 and 3T machines, can be paired with Attain Performa(TM) quadripolar lead technology. In addition to the new EffectivCRT features, the Claria device includes the Medtronic-exclusive AdaptivCRT(TM) algorithm, which has been shown to provide a 46 percent reduction in AF risk1 and reduce a patient's odds of a 30-day heart failure readmission by 59 percent2.

CRTee was a prospective, randomized, crossover study of 71 patients with paroxysmal, persistent or permanent AF. Sixty-six patients were randomized first to either an existing algorithm or the new EffectivCRT algorithm, with the desired outcome of a higher percent of effective CRT being delivered during AF. Fifty-four patients completed both arms. The EffectivCRT group increased effective pacing during AF by 7 percent, from 81 percent to 88 percent, p<0.001. Heart rate increased by only three beats-per-minute, from 77 to 80 BPM, p<0.001. Patients with a low percent of pacing at baseline (less than or equal to 80 percent) received the greatest benefit (average absolute increase of 15 percent effective pacing).

"Medtronic has made great strides in providing patients with a range of products that incorporate the most advanced technology available to improve CRT response," said David Steinhaus, M.D., vice president and general manager of the Heart Failure business, and medical director for the Cardiac Rhythm and Heart Failure division of Medtronic. "We are continually expanding our research and development to create better solutions for improved outcomes, based on individualized care in cardiac rhythm and heart failure devices."

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services of the highest quality that deliver clinical and economic value to healthcare

consumers and providers around the world.

About Medtronic

Medtronic plc (<u>www.medtronic.com</u>), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 88,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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- 1 Martin DO, et al. Clinical Outcomes with Adaptive Cardiac Resynchronization Therapy: Long-Term Outcomes of the Adaptive CRT Trial. *HFSA Late Breakers*. September 23, 2013.
- 2 Starling RC, Krum H, Bril S, et al. Impact of a Novel Adaptive Optimization Algorithm on 30-Day Readmissions: Evidence From the Adaptive CRT Trial. JACC Heart Fail. July 2015;3(7):565-572.

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